K092225

510(k) Summary
510(k) Premarket Notification

OCT - 9 2009

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:
Amylior Inc.
1650 Chicoine
Vaudreuil-Dorion, Quebec, Canada
J7V 8P2

FDA registration number of the manufacturer of the new device:
9615410

Official contact person for all correspondence:
Eric Dugas
President
Amylior Inc.
1650 Chicoine
Vaudreuil-Dorion, Quebec, Canada
J7V 8P2
Phone: 450-424-0288 Ext:223
Fax: 450-424-7211
Email: edugas@amysystems.com

Date Prepared: July 20th, 2009

Device Name: AMYPOWER ALLTRACK Series Power Wheelchair

Generic name of the device: Power Wheelchair

Classification of the predicate device: Class II

Classification of new device: Class II

Classification Panel: Physical Medicine

Panel Code: ITI

CFR Regulation Number: 21 CFR 890.3860

Predicate Device Name(s) and 510(k) number(s): Invacare Corporations' Storm TDX power wheelchair (K023589, 11/19/2002), and Invacare Storm Power wheelchair (K940051, 03/28/1994).

Description of Device:

The AMYPOWER ALLTRACK power wheelchair is a battery powered, motor driven device. It is a rigid or "non-folding" type power wheelchair design that offers functionality to be used as a mid wheel drive or a rear wheel drive base. The design offers a modular approach and can be configured in multiple versions to suit different client needs. The ALLTRACK series power wheelchair is designed to offer the ultimate in safety, stability, performance and comfort for the user. It features an active six wheel suspension as well as a seat suspension, and front and rear anti-tip casters which allow for surface contact of all six wheels at all times and prevents pitching on slopped terrain. The ALLTRACK power wheelchair utilizes components typically found on most wheelchairs, including but not limited to a rigid steel frame, a seat, armrests, front riggings, two main drive wheels, two electric drive motors, front & rear castors, two batteries, a charger, a positioning belt and a controller.

Comparison of Device Technological Characteristics to Predicate Devices:

This device has similar technological characteristics as the predicate devices. They all use steel and aluminum in their frames and components, and standard foams and covers for the slings, backs and cushions. The end-user controls the chair by using a joystick or other equivalent command mode through a controller. Motors use 2 x 12 volt DC rechargeable batteries as a source of energy. The operating speeds, maneuverability, power modules, hand controls, seat types, drive wheels, and climbing ability are substantially equivalent and are recommended for indoor and moderate outdoor use. The standard accessories and components are common to all power wheel chair devices.

Statement of Intended Use:

The intended use of the Amylior Inc. model AMYPOWER ALLTRACK series power wheelchair and other predicate devices is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. The AMYPOWER ALLTRACK series power wheelchair provides an optional means of mobility for physically challenged people.

Non-Clinical Testing:

This device has been tested to appropriate ISO & ANSI/RESNA standards and other applicable requirements passing all test protocols. As required by FDA's July 26, 1995 draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles", the AMYPOWER ALLTRACK series power wheelchair was tested in accordance with ISO EMC Standard 7176-14 and ANSI/RESNA WC vol.1 & vol. 2, Section 21:1998 amendments for powered wheelchairs and motorized scooters. In all instances, the AMYPOWER ALLTRACK series power wheelchair met the required performance criteria and functioned as intended.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the AMYPOWER ALLTRACK series power wheelchair to the Invacare Storm TDX power wheelchair (K023589, 11/19/2002), and Invacare Storm Power wheelchair (K940051, 03/28/1994), together with the results of testing demonstrates the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.

Conclusion:

The AMYPOWER ALLTRACK series power wheelchair has the same intended use and similar technological characteristics as the Invacare Storm TDX power wheelchair (K023589, 11/19/2002), and Invacare Storm Power wheelchair (K940051, 03/28/1994), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any concerns of safety or effectiveness. Thus, the AMYPOWER ALLTRACK series power wheelchair is substantially equivalent to the predicate devices. The AMYPOWER ALLTRACK series power wheelchair has passed all the necessary testing procedures and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Amylior Inc.
% Mr. Eric Dugas
President
1650 Chicoine Vaudreuil-Dorian
Quebec
Canda J7V 8P2

OCT - 9 2009

Re: K092225
Trade/Device Name: AMYPOWER ALL TRACK series power wheechair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: August 27, 2009
Received: August 27, 2009

Dear Mr. Dugas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

K

Device Name:

AMYPOWER ALLTRACK series power wheelchair

Indications for Use:

The AMYPOWER ALLTRACK power wheelchair's intended use is to provide mobility to persons limited to a seating position, that have the capability of operating a powered wheelchair. The AMYPOWER ALLTRACK power wheelchair empowers physically challenged individuals by providing a means of mobility.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092225